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510(k) Summary

SUPERA VERITAS®
Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

Submitter: IDEV Technologies, Inc.
253 Medical Center Boulevard
Webster, Texas 77598
281/525-2000

Contact Person: Darlene Garner
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Date Prepared: June 22, 2011

Trade Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

Common Name: Stent Delivery Catheter

Classification Name: Catheter, Biliary, Diagnostic; Class II

Product Code: FGE

Predicate Devices: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System (K093893)

Bard E-LUMINEXX® Biliary Stent (K063532)

Cordis S.M.A.R.T. ®Nitinol Stent Transhepatic Biliary System (K062798)

Device Description:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is a 0.014" or 0.018" guidewire compatible, multi-lumen sheath based delivery system and a SUPERA® Biliary Stent. The stent delivery catheter includes a radiopaque Stent Length Marker and Distal Sheath Marker embedded in the Outer Sheath to aid in proper stent positioning; a Thumb Slide connected internally for advancing the Stent out of the Outer Sheath while the Outer Sheath moves proximally in a de-coupled fashion; a Sheath Flush Port for flushing the central lumen of the device; a Deployment Lock that when actuated enables the final deployment stroke of the stent; a Guidewire Lumen with a radiopaque Catheter Tip located on the distal end of the Catheter Shaft; a Guidewire Flush Port used for flushing the Guidewire Lumen; a Stent Driver (ratchet) which moves the stent distally relative to the Outer Sheath; and the System Lock which eliminates the possibility of premature deployment. The working length of the delivery catheter is 80cm and 120cm.

The SUPERA® Stent is housed within the SUPERA VERITAS® stent delivery catheter and is a closed end interwoven self-expanding Nitinol stent. The SUPERA® stent is composed of 6 interwoven, closed loop Nitinol wires. The wire loops are closed via a proprietary welding process which utilizes small Nitinol tubes that act as a coupler to provide the mechanical means of joining the wire ends.

The table below includes the available sizes and model numbers for the **6Fr** SUPERA VERITAS Stent Delivery System.

Model No.	Stent Diameter	Stent Length	Catheter Length
S-04-040-80-6F	4mm	40mm	80cm
S-04-060-80-6F	4mm	60mm	80cm
S-04-080-80-6F	4mm	80mm	80cm
S-04-100-80-6F	4mm	100mm	80cm
S-04-120-80-6F	4mm	120mm	80cm
S-05-040-80-6F	5mm	40mm	80cm
S-05-060-80-6F	5mm	60mm	80cm
S-05-080-80-6F	5mm	80mm	80cm
S-05-100-80-6F	5mm	100mm	80cm
S-05-120-80-6F	5mm	120mm	80cm
S-06-040-80-6F	6mm	40mm	80cm
S-06-060-80-6F	6mm	60mm	80cm
S-06-080-80-6F	6mm	80mm	80cm
S-06-100-80-6F	6mm	100mm	80cm
S-06-120-80-6F	6mm	120mm	80cm
S-07-040-80-6F	7mm	40mm	80cm
S-07-060-80-6F	7mm	60mm	80cm
S-07-080-80-6F	7mm	80mm	80cm
S-07-100-80-6F	7mm	100mm	80cm
S-04-040-120-6F	4mm	40mm	120cm
S-04-060-120-6F	4mm	60mm	120cm
S-04-080-120-6F	4mm	80mm	120cm
S-04-100-120-6F	4mm	100mm	120cm

Model No.	Stent Diameter	Stent Length	Catheter Length
S-04-120-120-6F	4mm	120mm	120cm
S-05-040-120-6F	5mm	40mm	120cm
S-05-060-120-6F	5mm	60mm	120cm
S-05-080-120-6F	5mm	80mm	120cm
S-05-100-120-6F	5mm	100mm	120cm
S-05-120-120-6F	5mm	120mm	120cm
S-06-040-120-6F	6mm	40mm	120cm
S-06-060-120-6F	6mm	60mm	120cm
S-06-080-120-6F	6mm	80mm	120cm
S-06-100-120-6F	6mm	100mm	120cm
S-06-120-120-6F	6mm	120mm	120cm
S-07-040-120-6F	7mm	40mm	120cm
S-07-060-120-6F	7mm	60mm	120cm
S-07-080-120-6F	7mm	80mm	120cm
S-07-100-120-6F	7mm	100mm	120cm

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is a sterile (via Ethylene Oxide sterilization) device and is intended for single use only.

Intended Use:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

Comparison to Predicate Devices:

The 6Fr SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is substantially equivalent to the predicate devices: IDEV's 7Fr SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System (K093893); the Bard E-LUMINEXX® Biliary Stent (K063532) and the Cordis S.M.A.R.T® Nitinol Stent Transhepatic Biliary System (K062798).

A review of the product specifications concluded that there are no major differences in design, materials, performance, safety and product effectiveness. Substantial Equivalence to the predicate devices has been demonstrated via bench performance testing.

Non-clinical Testing:

Non-clinical testing were performed per the FDA's "Guidance of Premarket notification 510(k) Submissions for Short Term and Long Term Intravascular Catheters"; the "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; ISO 10555 - Sterile, Single-use Intravascular Catheters; and ISO 10993 - International Standard for Biological Evaluation of Medical Devices". Clinical data was not required in order to demonstrate safety and efficacy for the device modifications described in this 510(k).

Biocompatibility testing included:

Test	Results
Cytotoxicity	Pass
Klingman Maximization (NaCl and CSO extracts)	Pass
Intracutaneous Injection (NaCl and CSO extracts)	Pass
Systemic Injection (NaCl and CSO extracts)	Pass
Rabbit Pyrogen	Pass
Hemolysis	Pass
Thrombogenicity Study in Dogs	Pass
Complement Activation Assay (C3a and SC5b-9)	Pass
Unactivated Partial Thromboplastin Time (UPTT)	Pass

All biocompatibility testing was performed under the 21 CFR, Part 58 Good Laboratory Practice for Non-Clinical Laboratory Studies. All tests passed the acceptance criteria identified in the applicable protocols.

Performance Bench Testing included:

Test	Description of Test	Results
Biliary Radial Force	Comparison of the results of the SUPERA Stent deployed from a 6Fr SUPERA VERITAS Stent Delivery System to the Bard E-LUMINEXX in regards to compressive force (radial stiffness and radial strength) and expansive force (radial stiffness and radial strength.	Pass
Catheter Torque Strength	Performed to characterize the torque strength of the SUPERA VERITAS Stent Delivery system when the handle was rotated on its central axis	Pass
Deployment Testing	This following elements were assessed during deployment testing: Working length, ratchet release, Tensile, Leak, Introducer Compatibility, Guidewire Compatibility, Pushability/Flexibility, Trackability, Torque, Distal stent deployment and Accuracy, Thumb slide deployment force, Thumb slide retraction force and Deployed stent length accuracy	Pass
Particulate	Performed using USP <788>, Particulate Matter in Injections and AAMI TIR42, Evaluation of Particulates Associated with Vascular Medical Devices.	Pass

Performance bench testing demonstrated that the 6Fr SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is substantially equivalent to its predicate devices. No additional safety risks were observed during testing.

Conclusion:

The 6Fr SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System demonstrated to be substantially equivalent to the predicate devices based on design specifications and characteristics, principle of operation, indications for use and performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Darlene Garner
Regulatory Affairs Manager
IDEV Technologies, Inc.
253 Medical Center Boulevard
WEBSTER TX 77598

OCT 19 2011

Re: K111766
Trade/Device Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System
Regulation Number: 21 CFR § 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: September 29, 2011
Received: September 30, 2011

Dear Ms. Garner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (301) 796-6926. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111766

Device Name: The SUPERA™ VERITAS™ Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

FDA's Statement of the Indications for Use for device:

The SUPERA™ VERITAS™ Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111766